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# Stark vs. Speier: A Comparison of Federal and California Physician Self-Referral Laws

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# CALIFORNIA HEALTH LAW NEWS

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# A N N O U N C E M E N T S

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## CSHA 2009 FALL SEMINAR

The 2009 CSHA Fall Seminar will be held November 6, 2009 at the Renaissance Hotel, Los Angeles.

Fall Seminar brochures and registration forms are now available online at [www.csha.info](http://www.csha.info). The event will feature the popular annual legislative update. Other topics include an update on California professional licensing boards, including the Medical and Nursing Boards; Doing Business with a Distressed Company and detection and prevention of substance abuse which is eligible for special MCLE credit. Register by October 19, 2009 to receive the early bird discounted rate.

## CSHA MEMBER UPDATES

George "Jody" Root, Jr., Mary K. Norvell and Diane M. Racicot, three members of Procopio's health care group, were recognized as outstanding attorneys in the health care arena by Chambers and Partners in the 2009 edition of Chambers USA.

Abramson Church & Stave proudly announces its new name, Ottone Leach Olsen & Ray LLP.

## CSHA MENTOR PROGRAM

We are excited to announce the third year of the California Society for Healthcare Attorneys (CSHA) Mentor Program. We received great feedback from participants in last year's program. There are already many students interested in participating this year and we need your help to make the program a success.

Our mentor program is unique because it's intended to reach only those students with an interest in healthcare law. We arrange for an exchange of contact information. The mentor and mentee then decide the best way to make the relationship work. Whether it's lunch, coffee, e-mails, or phone calls, it doesn't take much to make this work.

If you are interested in participating, signing up is simple: just send a short email with your contact information and alma mater to Megan Shull, CSHA Program Manager, at [mshull@calhealth.org](mailto:mshull@calhealth.org). As students begin to sign up we will match you. If you participated in the past and are ready for an additional mentee, please let us know. We look forward to another successful year of this program!

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# STARK VS. SPEIER:

## A Comparison of Federal and California Physician Self-Referral Laws



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### INTRODUCTION

Over the last two decades, the federal government and many state governments have increasingly scrutinized the financial relationships between health care facilities and physicians who refer patients or business to them. Such relationships are prone to fraud and abuse because a physician may be more likely to make unnecessary referrals or otherwise over-utilize services if the relationship monetarily incentivizes him or her to do so. Over-utilization not only results in higher costs to patients and payors, but also may adversely affect patient care.

A 1989 study, conducted by the Office of Inspector General of the Department of Health and Human Services, found that physicians who owned or invested in independent clinical laboratories referred patients for 45 percent more laboratory services than did physicians who did not have such financial interests.<sup>1</sup> It was around the time of the study that the U.S. Congress began considering legislation to place restrictions on physician self-referrals.

In 1988, U.S. Representative Pete Stark (D – California) introduced the “Ethics in Patient Referrals Act” prohibiting physicians from making referrals for Medicare covered services to clinical laboratories with which the physician had a financial relationship, unless the action qualified for an appropriate exception. The law became effective in 1992, and was known as “Stark I.”<sup>2</sup> Congress subsequently added ten additional referral prohibitions, in legislation known as Stark II, effective as of January 1, 1995.<sup>3</sup> The Centers for Medicare and Medicaid Services (“CMS”), the agency responsible

for implementing and enforcing the Stark Law, promulgated various sets of regulations interpreting Stark I and II, culminating in the “Stark II, Phase III” regulations, which became effective December 4, 2007.<sup>4</sup> In addition, as recently as August 19, 2008, CMS published the 2009 Inpatient Prospective Payment System Final Rule (“IPPS Final Rule”),<sup>5</sup> which further revised the Stark Law.

The states have also become increasingly involved in monitoring and policing health care fraud and abuse related to physician self-referrals. California’s self-referral law, the Physician Ownership and Referral Act, more commonly referred to as the “Speier Law,” became effective in 1995. Like the Stark Law, the Speier Law prohibits a physician from referring a patient for certain health care services if he or she (or an immediate family member) has a financial interest with the entity receiving the referral, unless an enumerated exception applies.<sup>6</sup> Unlike the Stark Law, which applies only to services covered under federal programs, the Speier Law applies without respect to payor source. The Stark Law contains many exceptions without analogous exceptions in the Speier Law, and vice versa.

This article provides an overview of both the Stark Law and the Speier Law, highlights some of the most commonly used exceptions in both, and discusses significant differences between them. Table 1 provides a summary comparison of the Stark Law and the Speier Law and their most commonly used exceptions.



## STARK LAW OVERVIEW

The Stark Law prohibits a physician from referring Medicare patients for certain “designated health services” (“DHS”), to providers of such DHS, if the physician (or an immediate family member) has a direct or indirect financial relationship with the DHS provider, unless one or more exceptions apply to the arrangement.<sup>7</sup> The Stark Law also prohibits DHS providers from submitting claims to Medicare if the service was provided as a result of a prohibited referral.<sup>8</sup> Additionally, Stark mandates that all entities furnishing services for which payment may be made under Medicare submit information to CMS or to the OIG concerning their reportable financial relationships.

DHS includes several categories of services: clinical laboratory services; physical therapy, occupational therapy, and speech-language pathology services; radiology or other diagnostic services; radiation therapy services; durable medical equipment; parenteral and enteral nutrients, equipments and supplies; prosthetics, orthotics and prosthetic devices; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.<sup>9</sup>

A “financial relationship” exists where the physician has either an “ownership” or an “investment” interest in the DHS provider or where there is a “compensation arrangement” between the two.<sup>10</sup> A “compensation arrangement” includes any remuneration between the physician and the DHS provider, whether direct or indirect, overt or covert, in cash or in kind.<sup>11</sup>

The Stark Law contains numerous exceptions, which permit physician referrals despite the existence of an ownership or investment interest. Some of the most commonly used exceptions are discussed further in this article and are also listed in Table 1 at the end of the article.

## SPEIER LAW OVERVIEW

The Speier Law prohibits a physician from making referrals for the furnishing of certain defined health care goods and services to any entity with which the physician (or his or her immediate family member) has a financial relationship, unless a statutory exception applies to the arrangement.<sup>12</sup> The Speier Law also prohibits the referral recipient from presenting any claim for payment to the patient or to his or her third-party payor with respect to the defined health care goods or services rendered pursuant to a prohibited referral, regardless of payor source. The Speier Law mandates written disclosure of a financial interest to the patient, whether the referral is to an entity in which the physician has an ownership interest or to another physician within the same practice group.<sup>13</sup> The healthcare goods and services covered under the Speier law include: laboratory; diagnostic nuclear medicine; radiation oncology; physical therapy; physical rehabilitation; psychometric testing; home infusion therapy; and diagnostic imaging goods or services (including X-ray, CT, MRI, PET, mammography and ultrasound).

## SIGNIFICANT DIFFERENCES BETWEEN STARK AND SPEIER

### A. DESIGNATED SERVICES

The Stark Law’s DHS differ from the services covered under the Speier Law. One significant difference is that the Speier Law’s designated services do not include inpatient or outpatient hospital services. Conversely, the Speier Law includes “psychometric testing” and “home infusion therapy,” which are not Stark Law DHS.<sup>14</sup>

### B. PENALTIES

Under the Stark Law, no payment may be made under Medicare for services rendered pursuant to a prohibited referral. If such payment is made, the claimant is liable to the payor for a refund. In addition, the government may impose civil penalties up to \$15,000 for each service, for knowingly presenting a bill or a claim for a service for which payment may not be made. Further, any person who is required to meet a reporting requirement, but fails to do so, may be liable for up to \$10,000 for each day. There are additional civil penalties for physicians or entities who enter into a prohibited scheme, such as a cross-referral arrangement, where the primary purpose is to secure referrals by the physician to the entity. The civil penalties for such violations can be up to \$100,000 for each arrangement.



A Speier Law violation is a misdemeanor criminal offense, punishable by a fine up to \$5,000 for each offense. Additionally, upon conviction, the Medical Board of California ("MBC") may commence disciplinary proceedings if it determines that a physician engaged in unprofessional conduct. Cross-referral schemes are punishable by a fine of up to \$15,000 per violation, and associated disciplinary actions by the MBC.<sup>15</sup>

### COMMON EXCEPTIONS UNDER THE STARK LAW AND SPEIER LAW

The following is a summary of the more commonly used exceptions in the Stark Law and the analogous exceptions in the Speier Law.

#### A. PHYSICIAN IN-OFFICE ANCILLARY SERVICES

The Stark Law's in-office ancillary services exception permits referrals for physician services if: (1) the services are furnished personally by the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual who is supervised by the referring physician or by another physician in the group practice; and (2) the services are furnished in the same building, a centralized building that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services, or a centralized building that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).<sup>16</sup> The Speier Law's group practice exception permits referrals for services performed

within, and goods provided by, a physician's office or group practice.<sup>17</sup> The Speier Law's exception is sufficiently broad to cover most instances that would fall under the Stark exception.

#### B. WHOLE HOSPITAL EXCEPTION

Under Stark Law's "whole hospital" exception, a physician's ownership interest in a hospital does not constitute a financial relationship if: (1) the referring physician is authorized to perform services at the hospital, (2) effective for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify),<sup>18</sup> the hospital is not a specialty hospital, and (3) the ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital. The Speier Law contains a very broad "health facilities" exception that permits physicians to refer patients to health facilities with which they have a financial relationship as long as there is no compensation for referrals and any equipment lease between the parties meets the Speier Law lease exception. In most situations involving a physician's ownership interest in a hospital, this "health facilities" exception will apply.<sup>19</sup>

#### C. LEASE OF OFFICE SPACE OR EQUIPMENT

The Stark Law contains two distinct exceptions for the lease of office space and for the lease of equipment. Specifically, the Stark Law permits payments for the use of office space and equipment made by a lessee to a lessor if there is a rental or lease agreement where: (1) the lease is written, signed by the parties, and specifies the covered premises or equipment, (2) the term is at least one

year, (3) the space or equipment does not exceed that which is reasonable and necessary and is used exclusively by the lessee when being used by the lessee, (4) the rental charges are set in advance, based on fair market value, (5) the rental charges are not determined in a manner that takes into account the volume or value of any referrals,<sup>20</sup> and (6) the arrangement is commercially reasonable even if no referrals are made.<sup>21</sup>

The Speier Law contains a comparable exception that permits a lease of space or equipment between a licensee (physician) and the recipient of his or her referrals if the lease is written, has commercially reasonable terms, has a fixed periodic rent payment, has a term of one year or more, and the lease payments are not affected by either party's referral of any person or the volume of services provided by either party.<sup>22</sup>

#### D. PERSONAL SERVICES EXCEPTION

Both the Stark Law and the Speier Law provide an exception for "personal service" arrangements. The Stark Law exception permits remuneration from an entity if (1) there is a written agreement, signed by the parties, which specifies the services to be furnished by the physician to the entity, (2) the aggregate services do not exceed those that are reasonable and necessary, (3) the term of the agreement is for at least one year, (4) the compensation is set in advance, does not exceed fair market value, and does not take into account the volume or value of referrals.<sup>23</sup>

The Speier Law exception exempts a personal services arrangement between a physician (or an immediate family

member) and the recipient of his or her referrals if essentially the same requirements of the Stark Law "personal services" exception are met. In addition, the physician must provide written disclosure of the arrangement to the patient, including information indicating where he or she may file a complaint against the licensee or the immediate family member.<sup>24</sup>

#### E. PHYSICIAN RECRUITMENT

Another frequently relied-upon Stark Law exception pertains to physician recruitment. This exception permits a hospital to recruit a physician with incentives paid directly to the physician (or, more commonly, a medical group that is to employ the physician) necessary to induce the physician to relocate to the geographic area serviced by the hospital in order to become a member of the hospital's medical staff. In addition: (1) the arrangement must be set out in writing, (2) the arrangement must not be conditioned on the physician's referrals to the hospital, (3) the hospital may not determine the amount of the remuneration to the physician based on the volume or value of an actual or anticipated referrals by the physician, and (4) the physician must be allowed to establish staff privileges at any other hospital.<sup>25</sup> There is no corresponding exception in the Speier Law. However, the "health facilities" exception discussed above may apply, as long as there is no compensation for referrals and any equipment lease between the parties meets the lease exception.<sup>26</sup>

#### F. BONA FIDE EMPLOYMENT RELATIONSHIPS

Stark Law's "bona fide employment relationship" exception permits an employer to compensate a bona fide physician (or immediate family member) provided that: (1) the employment is for identifiable services, (2) the compensation is based on fair market value and does not take into account the volume or value of any referrals, and (3) the remuneration is provided under a commercially reasonable agreement even if no referrals were made to the employer.<sup>27</sup> Although there is no specific corresponding exception in the Speier Law, the "health facilities" exception is likely to apply in most employment circumstances where the hospital is the employer. Additionally, the "group practice" exception may apply in many arrangements between physicians and medical groups.<sup>28</sup>

#### G. EXCEPTIONS NOT FOUND IN THE SPEIER LAW

There are a number of additional exceptions in the Stark Law without specific corresponding sections in the Speier Law. These include: implants furnished by an ambulatory surgery center; EPO and other dialysis-related drugs; preventive screening tests, immunizations and vaccines, eyeglasses and contact lenses following cataract surgery; intra-family rural referrals, physician incentive plans; certain arrangements with hospitals; group practice arrangements with a hospital; payments by physicians; charitable donations by a physician; nonmonetary compensation; fair market value compensation; medical staff incidental benefits; risk-sharing

arrangements; compliance training; indirect compensation arrangements; referral services; obstetrical malpractice; professional courtesy; retention payments in underserved areas; community-wide health information systems. With respect to such arrangements between physicians and hospitals or other health facilities, the Speier Law's "health facilities" exception is likely to protect the arrangement in many cases.

In general, the Stark Law imposes greater burdens on providers than does the Speier Law to meet an applicable exception, and most Stark-compliant transactions will thus be Speier-compliant. However, health care entities should consult counsel to ensure that a proposed arrangement is acceptable under both laws.



TABLE 1

TOPIC	STARK II	SPEIER
BASIC PROVISIONS	<p>A physician may not refer a Medicare patient for “designated health services” if the physician (or an immediate family member) has a direct or indirect “financial relationship” with the entity receiving the referral. An entity may not present a claim or bill to Medicare for designated services referred to the entity by a physician with a “financial relationship” with the entity. § 411.353(a). DHS includes: (1) Clinical laboratory services; (2) physical, occupational and speech therapy; (3) radiology and certain other diagnostic services; (4) radiation therapy services and supplies; (5) durable medical equipment and supplies; (6) parenteral and enteral nutrients, equipment and supplies; (7) prosthetics, orthotics and prosthetic devices and supplies; (8) home health services; (9) outpatient prescription drugs; and (10) inpatient and outpatient hospital services. § 411.351.</p>	<p>It is unlawful for a physician to refer a patient for certain designated services if the physician (or immediate family member) has a “financial interest” with the entity receiving the referral. It is unlawful for an entity receiving an illegal referral to present a claim for payment to any payor including the patient and third party payors in the service. It is unlawful for a payor to pay a charge for services rendered from an illegal referral. It is unlawful to enter into cross referral arrangements. § 650.01(a). The covered services include: (1) Laboratory; (2) diagnostic nuclear medicine; (3) radiation oncology; (4) physical therapy; (5) physical rehabilitation; (6) psychometric testing; (7) home infusion therapy; and (8) diagnostic imaging goods or services (including X-ray, CT, MRI, PET, mammography and ultrasound). § 650.01(a).</p>
EFFECTIVE DATE	<p>January 1, 1995 (Similar legislation has been in effect since January 1, 1992 for clinical laboratory services).</p>	<p>January 1, 1995 The Speier legislation was amended in 1995 and 1996, and the amendments are retroactively effective on January 1, 1995.</p>

TOPIC	STARK II	SPEIER
<b>DEFINITIONS</b>		
“Financial relationship” under Stark; “Financial interest” under Speier	Includes: (1) an ownership or investment interest in an entity (through debt or equity); (2) a “compensation arrangement” between the physician (or family member) and the entity. A “compensation arrangement” is any arrangement involving remuneration, direct or indirect, between a physician and an entity. § 411.354.	Includes direct and indirect ownership interest, debts, loans, leases, compensation, remuneration, discount, rebate, refund, dividend, distribution, subsidy, or other form of direct or indirect payment, in money or otherwise. Excludes the receipt of capitation payments that are prepaid in exchange for a promise of a licensee to provide specified health care services to specified beneficiaries. Also excludes the receipt of remuneration by a medical director of a hospice, so long as the medical director agreement is in writing, has a term of at least one year, specifies the services to be provided and compensation is set in advance and is unrelated to referrals or other business between the parties. § 650.01(b)(2).
“Immediate family member”	A physician’s husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. § 411.351.	A licensee’s parent, spouse, child and spouse of child. § 650.01(b)(3).
“Physician” in Stark “Licensee” in Speier	Doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart. § 411.351.	M.D., D.O., psychologist, optometrist, dentist, podiatrist, acupuncturist or chiropractor. § 650.01(b)(4).
Characteristics of a “group practice”	Each group member provides substantially all of the patient care services throughout the shared resources of the group; substantially all group members’ services are billed and collected in the name of the group; and the income and expenses of the group are distributed in accordance with methods determined by the group. § 411.352.	An office or offices in which two or more licensees are legally organized as a partnership, professional corporation, or not-for-profit corporation, where each provides substantially the full range of services, substantially all of the services are billed in the name of the group; and the income and expenses of the group are distributed in accordance with methods determined by the group. § 650.01(b)(6).



TOPIC	STARK II	SPEIER
“Referral”	Request by a physician for an item or service, including consultation, which is paid for by Medicare. Requests by a pathologist for clinical lab or pathology services, by a radiologist for diagnostic radiology services, or by a radiation oncologist for radiation therapy are not deemed to be referrals if the services are furnished pursuant to a consultation by another physician. § 411.351.	Not defined. However, application requests by a pathologist for clinical lab or pathology services, by a radiologist for diagnostic radiology services, or by a radiation oncologist for radiation therapy are not deemed to be referrals if the services are furnished pursuant to a consultation by another physician. § 650.02(j).
“Fair Market Value” (FMV)	The value in arm’s-length transactions, consistent with the general market value. § 411.351.	Not defined.
<b>General exceptions to the referral prohibition related to both ownership/investment and compensation</b>		
Physician Services	Physicians’ services, including diagnosis, therapy, surgery, consultations, and home, office, and institutional calls, provided that the services are provided either: (1) personally by another physician who is a member of the referring physician’s group practice or is a physician in the same group practice as the referring physician; or (2) under the supervision of another physician who is a member of the referring physician’s group practice or is a physician in the same group practice as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services. “Physician services” includes only those “incident to” services that are physician services. § 411.355(a).	Any service for a specific patient that is performed within, or goods that are supplied by, a licensee’s office, or the office of a group practice. § 650.02(f).
Physician In-Office Ancillary Services	Services are permitted if: (1) The services are furnished personally by one of the following individuals: (a) the referring physician; (b) a physician who is a member of the same group practice as the referring physician; or (c) an individual who is supervised by the referring physician or by another physician in the group practice. (2) The services must be furnished in one of the following locations: (a) the same building, and meet one of three specific conditions (b) a centralized building that is used by the group practice for the provision of some or all of the group practice’s clinical laboratory services; or (c) a centralized building that is used by the group practice for the provision of some or all of the group practice’s DHS (other than clinical laboratory services). § 411.355(b).	Referrals are permitted for services performed within, and goods provided by, a physician’s office or group practice. § 650.02 (f).



TOPIC	STARK II	SPEIER
Exceptions to the referral prohibition related to ownership or investment interests		
Ownership Interest in Publicly Held Entities	The ownership or investment interest does not constitute a financial relationship where it involves the ownership of investment securities that at the time the DHS referral was made could be purchased on the open market and are either (1) listed on the NYSE, ASE, or any regional exchange, or foreign securities listed on a recognized exchange; or (2) traded under an automated interdealer quotation system operated by the NASD; and the interest is in a corporation that had shareholder equity exceeding \$75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. § 411.356(a).	Ownership in publicly held corporations if the corporation had in the most recent fiscal year, or on the average over the last three fiscal years, stockholder equity exceeding \$75 million; the interest is available to the general public through a licensed exchange; the corporation has no separate class of interest for referring physicians; and distributions are not affected by the value or volume of referrals. § 650.02(b)(3).
Mutual funds	Ownership of shares in a regulated investment company if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million. § 411.356(b).	Ownership of shares in a regulated investment company, if the company had, at the end of the company's most recent fiscal year, or on average during the previous three fiscal years, total assets exceeding \$75 million. § 650.02(b)(4).
Rural Providers	Ownership or investment in a rural provider in the case of DHS furnished in a rural area by the provider. § 411.356(c)(1).	A physician may refer a patient for a designated service if there is no alternative provider of the service within either 25 miles or 40 minutes shortest traveling time on a paved road. § 650.02(a).
Hospitals	A hospital that is located outside of Puerto Rico, in the case of DHS furnished by such a hospital, if -- (1) the referring physician is authorized to perform services at the hospital; (2) effective for the 18-month period beginning on 12/8/2003 (or such other period as Congress may specify), the hospital is not a specialty hospital; and (3) the ownership or investment interest is in the entire hospital and not merely in a distinct part of department of the hospital. § 411.356(c)(3). The specialty hospital moratorium ended June 8, 2005 and was not subsequently extended.	A licensee may refer a person to a health facility or any facility owned or leased by a health facility, if there is no compensation for referrals and any equipment lease between the parties meets the lease exception. Nothing shall preclude this subdivision from applying to a licensee solely because the licensee has an ownership or leasehold interest in an entire facility or an entity that owns or leases an entire health facility. § 650.02(c)(1).



TOPIC	STARK II	SPEIER
Exceptions to the referral prohibition related to compensation arrangements		
Rental of Office Space	<p>Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement where: (1) the lease is written, signed by the parties, specifying the covered premises; (2) the term is at least one year; (3) the space or equipment does not exceed that which is reasonable and necessary and is used exclusively by the lessee when being used by the lessee; (4) the rental charges are set in advance, based on FMV; (5) the rental charges are not determined in a manner that takes into account the volume or value of any referrals; and (6) the arrangement is commercially reasonable even if no referrals are made. § 411.357(a). In addition to rental charges not taking into account volume or value of referrals, as of October 1, 2009, rental charges over the term of the agreement also may not be determined “[u]sing a formula based on-- (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or (B) Per unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. § 411.357 (a).</p>	<p>A lease of space with a written lease with (1) commercially reasonable terms; (2) fixed periodic payments; (3) a term of one year or more; and (4) payments which are not affected by the value or volume of referrals between the parties. § 650.02(b)(2).</p>
Rental of Equipment	<p>Payments made by a lessee or lessor for the use of equipment where: (1) a rental or lease agreement is set out in writing, signed by the parties, specifying the equipment it covers; (2) the equipment rented or leased does not exceed that which is reasonable and necessary; (3) the agreement provides for a term of rental or lease of at least one year; (4) the rental charges are set in advance, consistent with FMV, and are not determined in a manner that take into account the volume or value of any referrals or other business generated between the parties; and (5) the agreement would be commercially reasonable even if no referrals were made between the parties. § 411.357(b). In addition to rental charges not taking into account volume or value of referrals, as of October 1, 2009, rental charges over the term of the agreement also may not be determined “[u]sing a formula based on-- (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or (B) Per unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. § 411.357 (a).</p>	<p>A lease of space with a written lease with (1) commercially reasonable terms; (2) fixed periodic payments; (3) a term of one year or more; and (4) payments which are not affected by the value or volume of referrals between the parties. § 650.02(b)(2).</p>



TOPIC	STARK II	SPEIER
Bona Fide Employment Relationships	Any amount paid by an employer to a physician who has a bona fide employment relationship with the employer for the provision of services provided that: (1) the employment is for identifiable services, (2) the amount of the remuneration under the employment is: (i) consistent with the fair market value of the services; (ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician; and (iii) the remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer. § 411.357(c).	No corresponding exception.
Personal Services Agreement	Remuneration from an entity under an arrangement or multiple arrangements where: (1) each arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement; (2) the arrangement covers all of the services to be furnished by the physician to the entity; (3) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement; (4) the term of each agreement is for at least 1 year; (5) the compensation is set in advance, does not exceed FMV, and is not determined in a manner that takes into account the volume or value of any referrals; (6) the services to be furnished do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law; and (7) a holdover personal services agreement (with the same terms and conditions in the immediately preceding agreement) is permitted for up to six months following the expiration of an agreement of at least one year that previously satisfied the requisite conditions. § 411.357(d)(1).	A personal services arrangement between a licensee or an immediate family member of the licensee and the recipient of the referral if the arrangement meets all of the following requirements: (1) is set out in writing and signed by the parties; (2) specifies all of the services to be provided by the licensee or an immediate family member of the licensee; (3) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement; (4) a person who is referred by a licensee or an immediate family member of the licensee is informed in writing of the personal services arrangement that includes information on where a person may go to file a complaint against the licensee or the immediate family member of the licensee; (5) the term of the arrangement is for at least one year; (6) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; and (7) the services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law. § 650.02(b)(6).



TOPIC	STARK II	SPEIER
Physician Recruitment	Remuneration provided by a hospital to recruit a physician that is paid directly to the physician and intended to induce the physician to relocate to the geographic area serviced by the hospital in order to become a member of the hospital's medical staff, provided: (1) the arrangement is set out in writing; (2) the arrangement is not conditioned on the physician's referrals to the hospital; (3) the hospital does not determine the amount of the remuneration to the physician based on the volume or value of an actual or anticipated referrals by the physician; and (4) the physician is allowed to establish staff privileges at any other hospital. § 411.357(e).	No corresponding exception. The "health facility" exception found in § 650.02(c) may apply.
Isolated Transactions	Isolated financial transactions, such as a one-time sale of property or a practice, provided: (1) the amount of the remuneration under the transaction is consistent with the FMV of the services; (2) the amount of remuneration is not determined in a manner that takes into account the volume or value of any referrals by the referring physician or other business generated between the parties; the remuneration would be commercially reasonable even if the physician made no referrals; there are no additional transactions between the parties for 6 months after the isolated transaction, unless otherwise excepted under the Stark provisions. § 411.357(f).	A one-time sale of a practice or property or other financial interest between a licensee and the recipient of the referral if the sale or transfer is for commercially reasonable terms and the consideration is not affected by either party's referral of any person or the volume of services provided by either party. § 650.02(b)(5).
Certain Arrangements with Hospitals	Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as "unrelated," remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. § 411.357(g).	No corresponding exception.
Group Practice Arrangements with a Hospital	A group practice's provision of DHS that are billed by the hospital if: (1) the arrangement has been in effect continuously since December 19, 1989; (2) at least 75% of these services furnished to hospital patients are furnished by the group; (3) the arrangement is in accordance with a written agreement that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement; and (4) compensation is consistent with fair market value, fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. § 411.357(h).	No corresponding exception.

TOPIC	STARK II	SPEIER
Payments by Physicians	Payments by a physician to a lab are made in exchange for clinical lab services, or by a physician to any entity for other items or services if the payments are consistent with the fair market value of the items and services. § 411.357(i).	No corresponding exception.
Charitable Donations by a Physician	Bona fide charitable donations made by a physician (or immediate family member) to an entity provided certain conditions are satisfied. § 411.357(j).	No corresponding exception.
Nonmonetary Compensation	Items or services (not including cash or cash equivalents) that do not exceed an aggregate of \$300 per year (adjusted for inflation) provided that: (1) the compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician; (2) the compensation may not be solicited by the physician or the physician's practice (including employees and staff members); and (3) the compensation arrangement does not violate the Federal anti-kickback statute or any Federal or State law or regulation governing billing or claims submission. § 411.357(k).	No corresponding exception.
Fair Market Value Compensation	An arrangement between an entity and a physician (or immediate family member) or any group of physicians for the provision of items of services (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, provided the following conditions are satisfied: (1) the agreement is in writing, signed by the parties, and covers only identifiable items of services, all of which are specified in the agreement; (2) the writing specifies the timeframe for the arrangement; (3) the writing specifies the compensation that will be provided under the agreement; (4) the arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties; (5) the arrangement does not violate the anti-kickback statute, or any Federal or State law or regulation; and (6) the services to be performed do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law. § 411.357(l). In addition to compensation not taking into account the volume or value of referrals, as of October 1, 2009, compensation may not be determined using a formula based on –(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated through the use of the equipment; or (ii) per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. § 411.357(l)	No corresponding exception.



TOPIC	STARK II	SPEIER
Medical Staff Incidental Benefits	<p>Compensation in the form of items or services from a hospital to a member of its medical staff when the item or service is used in the hospital's campus, provided: (1) the compensation is offered to all members of the medical staff practicing in the same specialty without regard to the volume or value of referrals; (2) the compensation is provided only during periods when the medical staff members are making rounds or engaged in other services that benefit the hospital; (3) the compensation is provided by the hospital and used by the medical staff members only on the hospital's campus; (4) the compensation is reasonably related to the provision of medical services at the hospital; (5) the compensation is of low value; (6) the compensation does not take into account the volume or value of referrals; and (7) the compensation agreement does not violate the anti-kickback statute. § 411.357(m).</p>	No corresponding exception.
Indirect Compensation Arrangements	<p>Indirect compensation agreements, provided: (1) the compensation received by the referring physician is FMV for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals; and (2) the compensation agreement is set out in writing, signed by the parties, and specifies the services covered by the arrangement. § 411.357(p). As of October 1, 2009, "[c]ompensation for rental of office space or equipment may not be determined using a formula based on--(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or (B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. § 411.357(p)</p> <p>An indirect compensation arrangement exists if --</p> <p>(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);</p>	No corresponding exception.

TOPIC	STARK II	SPEIER
Indirect Compensation Arrangements (cont.)	<p>(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and</p> <p>(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.</p> <p>(iv)(A) For purposes of paragraph (c)(2)(i) of this section, except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to “stand in the shoes” of his or her physician organization if the physician has an ownership or investment interest in the physician organization.</p> <p>(B) For purposes of paragraph (c)(2)(i) of this section, a physician (other than a physician described in paragraph (c)(2)(iv)(A) of this section) is permitted to “stand in the shoes” of his or her physician organization.</p>	



TOPIC	STARK II	SPEIER
Indirect Compensation Arrangements (cont.)	<p>(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv), a physician who “stands in the shoes” of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. For purposes of applying the exceptions in § 411.355 and § 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the “parties” to the arrangements are considered to be the entity furnishing DHS and the physician organization (including all members, employees, or independent contractor physicians).</p> <p>(ii) The provisions of paragraphs (c)(1)(ii) and (c)(2)(iv)(A) of this section--</p> <p>(A) Need not apply during the original term or current renewal term of an arrangement that satisfied the requirements of § 411.357(p) as of September 5, 2007 (see 42 CFR Parts 400-413, revised as of October 1, 2007);</p> <p>(B) Do not apply to an arrangement that satisfies the requirements of § 411.355(e); and</p> <p>(C) Do not apply to a physician whose ownership or investment interest is titular only. A titular ownership or investment interest is an ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.</p> <p>(iii) An arrangement structured to comply with an exception in § 411.357 (other than § 411.357(p)), but which would otherwise qualify as an indirect compensation arrangement under this paragraph as of August 19, 2008, need not be restructured to satisfy the requirements of § 411.357(p) until the expiration of the original term or current renewal term of the arrangement. § 411.354(c)(2).</p>	

TOPIC	STARK II	SPEIER
Professional Courtesy	Professional courtesy offered by an entity with a formal medical staff to a physician or a physician's immediate family member or office staff if all of the following conditions are met: (1) the professional courtesy is offered to all physicians on the entity's bona fide medical staff or in such entity's local community or service area without regard to the volume or value of referrals or other business generated between the parties; (2) the health care items and services provided are of a type routinely provided by the entity; (3) the entity has a professional courtesy policy that is set out in writing and approved in advance by the entity's governing body; (4) the professional courtesy is not offered to a physician who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need; and the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. § 411.357(s).	No corresponding exception.
Electronic Prescribing Items and Services	Nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information, provided certain conditions are satisfied. § 411.357(v).	Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful to provide nonmonetary remuneration, in the form of hardware, software, or information technology and training services, as described in subsections (x) and (y) of Section 1001.952 of Title 42 of the Code of Federal Regulations, as amended October 4, 2007, as published in the Federal Register (72 Fed. Reg. 56632, 56644), and subsequently amended versions. § 650(e).



TOPIC	STARK II	SPEIER
Electronic Health Records Items and Services	Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, provided certain conditions are satisfied. § 411.357(w).	Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful to provide nonmonetary remuneration, in the form of hardware, software, or information technology and training services, as described in subsections (x) and (y) of Section 1001.952 of Title 42 of the Code of Federal Regulations, as amended October 4, 2007, as published in the Federal Register (72 Fed. Reg. 56632, 56644), and subsequently amended versions. § 650(e).
Nonprofit Corporation	No corresponding exception.	A licensee may refer to a non-profit corporation that provides physician services if the clinic is controlled by a health facility system and physician compensation is fixed annually and is not based on patient volume or utilization. § 650.02(d).
Multi-specialty Clinic	No corresponding exception.	A licensee, if in the office of a group practice, may refer a person for services or goods, to a multi-specialty clinic. § 650.02(h).
Loans	No corresponding exception.	A loan with commercially reasonable terms, that bears interest at least the prime rate, is adequately secured, and which has a repayment obligation that is not affected by the value or volume of referrals between the parties. § 650.02(b)(1).
Cardiac Rehabilitation	No corresponding exception.	Cardiac rehabilitation services provided by a licensee or by a suitably trained individual under the direct or general supervision of a licensee, if the services are provided to patients meeting the criteria for Medicare reimbursement for the services. § 650.02(g).

TOPIC	STARK II	SPEIER
Pathologist, Radiologist, Radiation Oncologist	A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a "referral" by a "referring physician". 42 U.S.C. 1395nn (h)(5)(C).	A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, or a request by a radiation oncologist for radiation therapy if those services are furnished by, or under the supervision of, the pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician. § 650.02(j).
Emergency care	No corresponding exception.	Referrals for emergency care services are permitted. § 650.02(c)(3).
<b>SANCTIONS</b>  Prohibited referrals	No payment can be made for services rendered; if payment is made, it must be refunded.  Civil penalty of up to \$15,000 for each service.  Exclusion from participation in Federal health care programs.  Civil penalty of \$10,000 per day for failure to comply with reporting requirements (see below). § 411.361(f).	Misdemeanor, with punishment of up to \$5,000 for each offense.  Upon conviction, the Medical Board may take disciplinary action if it finds a physician engaged in unprofessional conduct. § 650.01(g).
<b>DISCLOSURE AND REPORTING REQUIREMENTS</b>	All entities furnishing services for which payment may be made under Medicare must submit information to CMS or to the OIG concerning their reportable financial relationships in the form, manner, and at the times OIG or CMS specifies. § 411.361.	Where referrals are permitted, there must be written disclosure of a financial interest to the patient, or the parent or legal guardian of the patient, whether the referral is to an entity in which the physician has an ownership interest or the referral is to another physician within the same practice group. § 650.01(f).
Cross referrals, presentations or payment of claims for illegal referrals.	Denial of payment. Persons who received payment in violation of the statute must reimburse Medicare. Civil penalty of \$15,000 per service. Civil penalty of up to \$100,000 if intent to circumvent rules. Exclusion from participation.	Up to \$15,000 per violation and disciplinary action by appropriate government licensing agency. § 650.01(g).



## ENDNOTES

1 Financial Arrangements Between Physicians and Health Care Businesses, OAI-12-88-01410.

2 The bill was incorporated as part of the Omnibus Budget Reconciliation Act of 1990.

3 42 C.F.R. § 411.350 through § 411.389.

4 72 Fed. Reg. 50102 (Sept. 5, 2007)

5 73 Fed. Reg. 48433 (Aug. 19, 2008).

6 Cal. Bus. & Prof. Code § 650.01.

7 42 C.F.R. § 411.350(a).

8 42 C.F.R. § 411.353(b).

9 42 C.F.R. § 411.351.

10 42 C.F.R. § 411.354(a).

11 42 C.F.R. § 411.354(c).

12 Cal. Bus. & Prof. Code § 650.01(a).

13 Cal. Bus. & Prof. Code § 650.01(f).

14 Cal. Bus. & Prof. Code § 650.01(a).

15 Cal. Bus. & Prof. Code § 650.01(g).

16 42 C.F.R. § 411.355(b).

17 Cal. Bus. & Prof. Code § 650.02(f).

18 The moratorium ended on June 8, 2005 and has not been subsequently extended.

19 Cal. Bus. & Prof. Code § 650(d).

20 In addition to rental charges not taking into account volume or value of referrals, as of October 1, 2009, rental charges over the term of the agreement also may not be determined "[u]sing a formula based on-- (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or (B) Per unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

42 C.F.R. § 411.357 (a).

21 42 C.F.R. § 411.357.

22 Cal. Bus. & Prof. Code § 650.02(b)(2).

23 42 C.F.R. § 411.357(d)(1).

24 Cal. Bus. & Prof. Code § 650.02(b)(6)(D).

25 42 C.F.R. § 411.357(e).

26 Cal. Bus. & Prof. Code § 650.02(c)(1).

27 42 C.F.R. § 411.357(c).

28 It should be noted with regard to the employment of physicians by hospitals that California is one of the states that currently has a corporate practice of medicine prohibition. This prohibition essentially makes it illegal for lay persons or entities to exercise ownership or control over a physician's practice. Cal. Bus. & Prof. Code §§ 2000 *et seq.*

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# A C K N O W L E D G E M E N T S

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*By Frederick D. Melendres, R. Gregory Cochran and Anamika D. Ghista*

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